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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,566	10/16/2001	Ramesh Kekuda	21402-163 (Cura-463)	7700

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EXAMINER	
HOWARD, ZACHARY C	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,566	KEKUDA ET AL.	
	Examiner	Art Unit	
	Zachary C Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-52 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C 121:

I. Claims 1-4, 38, and 41, drawn to isolated GPCR1-12 polypeptides, compositions comprising the polypeptides, and kits comprising the compositions, classified in class 530, subclass 350, for example.

II. Claims 5-14, 39, and 42, drawn to isolated nucleic acids encoding GPCR1-12 polypeptides, vectors, host cells, compositions comprising the nucleic acids, and kits comprising the compositions, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3, and 69.1, for example.

III. Claims 15-17, 40, and 43, drawn to antibodies which selectively bind GPCR1-12 polypeptides, compositions comprising the antibodies, and kits comprising the compositions, classified in class 530, subclass 388.22, for example.

IV. Claims 18, 44, and 45, drawn to methods of determining the presence or amount of GPCR1-12 polypeptides in a biological sample, classified in class 435, subclass 7.1, for example.

V. Claims 19-21, 46, and 47, drawn to methods of determining the presence or amount of nucleic acids encoding GPCR1-12 polypeptides in a biological sample, classified in class 435, subclass 6, for example.

VI. Claims 22-24 and 50-52, drawn to a method of identifying an agent that binds to, or modulates expression or activity of GPCR1-12 polypeptides, classified in class 435, subclass 7.1, for example.

VII. Claim 25, drawn to a method for modulating the activity of a cell sample with an agent which binds GPCR1-12 polypeptides, classified in class 424, subclass 139.1, for example.

VIII. Claims 26-29 and 48, drawn to a method of treatment comprising administering GPCR1-12 polypeptides, classified in class 514, subclass 12, for example.

IX. Claims 30-33, drawn to a method of gene therapy comprising administering nucleic acids encoding GPCR1-12 polypeptides, classified in class 514, subclass 44, for example.

X. Claims 34-37 and 49, drawn to a method of treatment comprising administering antibodies which selectively bind to GPCR1-12 polypeptides, classified in class 514, subclass 2, for example.

3. The inventions are distinct, each from the other because of the following reasons:

Each of the inventions I, II and III are unrelated to each of the other inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides, nucleic acids and antibodies are all physically and functionally distinct chemical entities that have different structures, activities and functions.

Invention I is related to invention IV in that the polypeptides are detected in the methods, however the polypeptides can also be used in methods of identifying an agent that binds to or modulates expression or activity of the polypeptides, or a method of treatment comprising administering the polypeptides, which are materially different methods.

Invention I is related to each of inventions VI and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be also be used in a method to determine the presence or amount of the polypeptides in a biological sample.

Invention I is unrelated to each of inventions V, VII, IX, and X. The polypeptides are not used in a method of determining the presence or amount of nucleic acids in a

biological sample, a method for modulating a cell sample by a compound that binds to the polypeptides, a method for gene therapy comprising administering nucleic acids, or in a method of treatment comprising administering antibodies.

Invention II is related to invention V in that the nucleic acids are detected in the methods, however the nucleic acids can also be used in a method of gene therapy comprising administering nucleic acids, which are materially different methods.

Invention II is related to invention IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids can also be used in a method of determining the presence or amount of nucleic acids in a biological sample.

Invention II is unrelated to each of inventions IV, VI, VII, VIII and X. The nucleic acids are not used in a method to determine the presence or amount of the polypeptides in a biological sample, a method of identifying an agent that binds to or modulates expression or activity of the polypeptides, a method for modulating a cell sample by a compound that binds to the polypeptides, a method of treatment comprising administering the polypeptides, or in a method of treatment comprising administering antibodies, which are materially different methods.

Invention III is related to each of inventions IV, VII and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in a method to determine the presence or amount of the polypeptides in a biological sample, a method for modulating a cell sample by a compound that binds to the polypeptides, or in a method of treatment comprising administering antibodies, which are materially different methods.

Invention III is unrelated to each of inventions V, VI, VIII and IX. The antibodies are not used in a method of determining the presence or amount of nucleic acids in a biological sample, in a method of identifying an agent that binds to or modulates expression or activity of the polypeptides, in a method of treatment comprising administering the polypeptides, or in a method of gene therapy comprising administering nucleic acids.

Inventions IV-X are unrelated to each other. The methods of the inventions require different starting products, have different methods steps and goals, and are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements and/or divergent subject matter, restriction for examination purposes as indicated is proper.

Further Restriction Within Groups I-X

For whatever group is elected, further restriction within the elected group is required, as follows: one of GPCR 1-12 polypeptides, polynucleotides, or antibodies.

Although classifications for the nucleic acids, proteins, antibodies are overlapping, for instance 536/23.1, each represents a patentably distinct product, having different sequences and structures and requiring separate sequence searches. Therefore, the methods of using the nucleic acids, proteins and antibodies are also patentably distinct.

Further restriction

If the elected GPCR has more than one form, for example GPCR1 with forms 1a-1f, further restriction within the elected group is required, as follows: one form, for example one of GPCR1a, GPCR1b, GPCR1c, GPCR1d, GPCR1e, or GPCR1f. If applicants can demonstrate (for example by sequence alignments) that the different forms are closely related and would not provide a search burden, the forms will be examined.

Applicants are advised that this is not a species election.

A telephone call was made to Greg Sieczkiewicz on April 21, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder under Ochiai/Brouwer

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined

process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Eileen B. O'Hara